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RECORD NO.

085702
SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

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TYPE PRODUCT(S): I, D, H, F, N, R, S Frost Protection Agent

DATA ACCESSION NO(S). 407104,-5,-6,-7,-8,-9

PRODUCT MANAGER NO. R.Mountfort (23)

PRODUCT NAME(S) ENFROST (Urea)

COMPANY NAME Unocal Chemicals Division

SUBMISSION PURPOSE New Chemical Registration for use as Frost Protection Agent on Wide Variety of Crops

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
085702	Urea (aqueous)	43.7%

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: New Chemical Registration for ENFROST

FROM: Zigfridas Vaituzis, Microbiologist
Ecological Effects Branch (H7507C)
Environmental Fate and Effects Division

THRU: Raymond W. Matheny, Head Section I
Ecological Effects Branch (H7507C)
Environmental Fate and Effects Division

THRU: James W. Akerman, ~~Chief~~
Ecological Effects Branch (H7507C)
Environmental Fate and Effects Division

TO: Richard Mountfort (23)
Herbicide/Fungicide Branch
Registration Division (H7505C)

Enclosed is the Ecological Effects Branch Science Chapter for the New Chemical Registration of ENFROST (urea) as a frost protection agent on various food crops.

ECOLOGICAL EFFECTS TOPICAL SUMMARY

A. Effects on Birds

The following avian studies were reviewed by EEB and are acceptable for hazard evaluation:

Author(s)	Date	MRID Number
Grimes, Jaber	1986	407107-01
Grimes, Jaber	1986	407108-01
Grimes, Jaber	1986	407109-01

The minimum data required to evaluate the hazard of urea to birds are:

1. An avian single dose oral LD_{50} test with the technical grade of the active ingredient utilizing either one species of waterfowl, preferably the mallard duck, or one species of upland game bird, preferably the bobwhite quail; and

2. Two avian dietary LC_{50} tests with the technical grade of the active ingredient utilizing one species of waterfowl, preferably the mallard duck, and one species of upland game bird, preferably the bobwhite quail.

1. Avian Single-Dose Oral LD_{50} - Technical Grade

The following avian acute oral study is suitable for assessing the hazard of urea:

Species	% ai	LD_{50} (mg/kg)	Author	Date	MRID Number	Toxicity	Fulfills Guideline Requirements
Bobwhite Quail	43.7%	>2250	Grimes Jaber	1986	407108-01	practically non-toxic	Yes

2. Avian Dietary LC_{50} - Technical

The following avian dietary studies are suitable for assessing the hazard of urea:

Species	% ai	LD_{50} (mg/kg)	Author	Date	MRID Number	Toxicity	Fulfills Guideline Requirements
Mallard Duck	43.7%	>5620	Grimes Jaber	1986	407107-01	practically non-toxic	Yes
Bobwhite Quail	43.7%	>5620	Grimes Jaber	1986	407109-01	practically non-toxic	Yes

These data indicate that urea is practically nontoxic to avian species. The Guidelines requirements for avian hazard assessment have been fulfilled.

3. Precautionary Labeling

Since urea is practically nontoxic to avian wildlife, no pracautionary labeling will be recommended at this time.

B. Effects on Freshwater Fish

The following freshwater fish studies were reviewed by EEB and are acceptable for hazard evaluation:

Author(s)	Date	MRID Number
Bowman, J.	1986	407104-01
Bowman, J.	1986	407106-01

The minimum data required to evaluate the hazard of urea to freshwater fish are:

1. Two 96-hour freshwater fish toxicity tests. One test should utilize a coldwater species, preferably the rainbow trout, and the other should utilize a warmwater species, preferably the bluegill sunfish.

2. When direct exposure of aquatic organisms to a chemical is expected, the formulated product testing is required.

1. Freshwater Fish LC_{50} - Technical

The following freshwater fish studies are suitable for assessing the hazard of urea:

Species	% ai	LC_{50} (ppm)	Author	Date	MRID Number	Toxicity	Guideline Requirements
Bluegill Sunfish	43.7%	>1000	Bowman	1986	407104-01	practically nontoxic	Yes
Rainbow Trout	43.7%	>1000	Bowman	1986	407106-01	practically nontoxic	Yes

The above data indicate that urea is practically nontoxic to both coldwater and warmwater fish species. The Guideline requirement for acute toxicity testing of urea on freshwater fish is fulfilled.

2. Acute Studies - Formulated Products

Acute aquatic toxicity studies on fish with formulated products may be required when the product will be introduced directly into water or when the estimated environmental concentration (EEC) exceeds the LC_{50} of the technical material to fish. Since urea is registered for terrestrial uses, is biodegradable and the freshwater fish LC_{50} is >1000 ppm, aquatic studies using the formulated product are not required at this time.

3. Precautionary Labeling

Since urea is practically nontoxic to both coldwater and warmwater fish species, no precautionary labeling will be recommended at this time.

C. Effects on Freshwater Aquatic Invertebrates

The following freshwater aquatic invertebrate study was reviewed by EEB and is acceptable for hazard evaluation:

Author	Date	MRID Number
Frazier, S.	1986	407105-01

The minimum data required to assess the hazard of urea to freshwater aquatic invertebrates is a 48-hour acute toxicity study, using the technical grade of the active ingredient, on first instar Daphnia magna or early instar amphipods, stoneflies, or mayflies.

When there is expected to be direct exposure of aquatic organisms to a chemical, formulated product testing is required.

1. Invertebrate Acute LC_{50} - Technical

The following freshwater invertebrate study is suitable for assessing the hazard of urea:

Species	% ai	LC_{50} (ppm)	Author	Date	MRID Number	Toxicity	Guideline Requirements
Daphnia magna	43.7%	>1000	Frazier	1986	407105-01	practically nontoxic	Yes

The above data indicate that urea is practically nontoxic to aquatic invertebrate species. The Guideline requirement for acute toxicity testing of the urea on freshwater aquatic invertebratres is fulfilled.

2. Acute Studies - Formulated Products

Acute aquatic toxicity studies on freshwater invertebrates with formulated products may be required when the product will be introduced directly into water or when the estimated environmental concentration (EEC) exceeds the LD_{50} of the technical material to freshwater invertebrates. Since urea is registered for terrestrial uses, is biodegradable and the freshwater invertebrate LC_{50} is >1000 ppm, aquatic studies using the formulated product are not required at this time.

3. Precautionary Labeling

Since urea is practically nontoxic to aquatic invertebrate species, no pracautionary labeling will be recommended at this time.

D. Effects on Estuarine and Marine Organisms

No studies were received under this topic.

Acute toxicity testing with estuatrine and marine organisms is required for a chemical when the TEP is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations when the product is used as directed. Urea is not expected to enter the estuarine environment in significant concentration as a result of the registered uses.

1. Technical Material

No studies were submited. There are no Guideline requirements for estuarine and marine studies on urea at this time.

E. Plant Protection

Target Area Phytotoxicity data for any site may be required for Special Review and certain public health situations when phytotoxicity is of concern.

All Tier I data on Nontarget Area Phytotoxicity are required for pesticides used in forests and natural grasslands. In addition, all Tier I data are required on the above and for other sites when any of the following conditions are met:

1. Phytotoxicity problems concerning the pesticide arise and open literature data are not available to address the problem.

2. The pesticide may pose problems to endangered or threatened species.

3. Special review has been initiated on the pesticide as a result of phytotoxicity.

There are no plant protection Guidelines requirements for the registered uses of urea at the present time.

ECOLOGICAL EFFECTS DISCIPLINARY REVIEW

I. ECOLOGICAL EFFECTS PROFILE

A. Technical Product

1. Terrestrial Studies

The reviewed data indicate that urea is practically nontoxic to avian species. No avian hazard is expected from the proposed uses of the product.

2. Aquatic Studies

The revieved data indicate that urea is practically nontoxic to aquatic species. No risk to aquatic wildlife is expected from the proposed uses of the product.

3. Plant studies

There are no plant protection Guidelines requirements for the registered uses of urea at the present time.

4. Toxicity to Estuarine and Marine Organisms

There is no requirement for this testing of urea products at this time.

B. Formulated Products and Use

Formulation:

ENFROST

Urea	43.7%
Phosphoric acid	0.3%
Phenol Red	0.0005%
Water	55.9%
Total	100.0%

ENFROST is produced by a method that removes phytotoxic impurities normally associated with the manufacture of urea. ENFROST provides plant frost protection by modifying the protein produced by ice-nucleating bacteria.

Use Sites, Rates and Application

ENFROST may be applied by ground equipment or by air. Applications are to be made when the air temperatures are expected to fall below 32°F. Repeat applications are necassary after a 4 to 7 day interval if cold temperatures persist.

Application Rates:

Crop	Gallons per acre
Deciduous tree	3 to 5
Nondeciduous tree	15
Specialty crops	5
Vegetable	5
Cole	10 to 20
Leafy vegetables	5
Peppers	5
Field crops	5
Vine crops	5
Melons	5
Nursery crops	5
Seed crops	5

II. RISK ASSESSMENT

No risk to nontarget wildlife is expected from the proposed uses of urea.

III. ENDANGERED SPECIES CONSIDERATIONS

No risk to endangered/threatened species is expected from the proposed uses of urea.

IV. PRECAUTIONARY STATEMENTS

A. Manufacturing-Use Products/End Uses Where an Effluent is Likely

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Reginal Office of the EPA.

B. End-Use Products

Do not contaminate water when disposing of equipment washwaters.

C. Endangered Species Labeling

There is no endangered species labeling requirement at this time.

V. MAJOR DATA GAPS

None. Please see Generic Data Requirements Table.

Generic Data Requirements For Urea

Data Requirement	Test Substance 1/	Use Patterns 2/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms						
Avian and Mammalian Testing						
71-1 - Avian Acute Oral Toxicity						
- Upland game bird	TGAI	A	Yes	407108-01	No	
71-2 - Avian Subacute Dietary Toxicity						
- Upland game bird	TGAI	A	Yes	407109-01	No	
- Waterfowl	TGAI	A	Yes	407107-01	No	
71-3 - Wild Mammal Toxicity	TGAI	A	No		No	
71-4 - Avian Reproduction						
- Upland game bird	TGAI	A	No		No	
- Waterfowl	TGAI	A	No		No	
71-5 - Simulated and Actual Field Testing for Mammals and Birds	TEP	A	No		No	
Aquatic Organisms Testing						
72-1 - Freshwater Fish Toxicity						
- Warmwater	TGAI	A	Yes	407104-01	No	
- Coldwater	TGAI	A	Yes	407106-01	No	

Generic Data Requirements For Urea (Cont'd)

Data Requirement	Test Substance 1/	Use Patterns 2/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms						
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A	Yes	407105-01	No	
72-3 - Acute Toxicity to Estuarine and Marine Organisms						
- Fish	TGAI	A	No		No	
- Shrimp	TGAI	A	No		No	
- Oyster	TGAI	A	No		No	
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life Cycle						
- Fish	TGAI	A	No		No	
- Invertebrates	TGAI	A	No		No	
72-5 - Fish Life Cycle	TGAI	A	No		No	
72-6 - Aquatic Organism Accumulation	TGAI	A	No		No	
72-7 - Simulated or Actual Field Testing						
- Aquatic Organisms	TEP	A	No		No	

Footnotes

1/TGAI = Technical Grade of the Active Ingredient; TEP = Typical End-Use Product.
2/The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic, Outdoor; I = Indoor.

ENVIRONMENTAL FATE DATA REQUIREMENTS

CHEMICAL: Urea

USE PATTERN: Terrestrial, Food Crop

STUDIES	REQUIRED	SUBMITTED	PASSED	WAIVER REQUESTED	WAIVER GRANTED
161.1 Hydrolysis	Yes	No	N/A	Yes	Yes (8/15/88)
Photodegradation:					
161-2 In water	Yes	No	N/A	Yes	Yes (8/15/88)
161-3 On soil	Yes	No	N/A	Yes	Yes (8/15/88)
161-4 In air	Yes	No	N/A	Yes	Yes (8/15/88)
Soil Metabolism:					
162-1 Aerobic	Yes	No	N/A	Yes	Yes (8/15/88)
162-2 Anaerobic	Yes	No	N/A	Yes	Yes (8/15/88)
Mobility in soil					
163-1 Leaching and Adsorption/Desorption	Yes	No	N/A	Yes	Yes (8/15/88)
164-1 Soil Dissipation	Yes	No	N/A	Yes	Yes (8/15/88)
Accumulation:					
165-1 Rotational crops (confined)	Yes	No	N/A	Yes	Yes (8/15/88)
165-4 In fish	Yes	No	N/A	Yes	Yes (8/15/88)

REVIEWER: Silvia C. Termes
Chemist
Review Section #3, EAB

Signature: [signature]

Date: August 15 1988

APPROVED BY: Emil Regelman
Supervisory Chemist
Review Section #3, EAB

Signature: [signature]

Date: AUG 15 1988